Serial No.	09/810,988
Applicant:	Gerhard Scheuch *et al.*
Filed:	March 16, 2001
Title:	DEVICE FOR THE CONTROLLED INHALATION OF THERAPEUTIC AEROSOLS
Art Unit:	3731
Examiner:	Glenn K. Dawson
Confirmation Number:	7304
Attorney Docket No.:	RVOS-E1341US

HONORABLE COMMISSIONER OF PATENTS
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

In response to the Office Action dated February 20, 2008, I, William C. Zimlich, Jr., do hereby declare and say as follows:

BACKGROUND INFORMATION

1. I am a co-inventor of U.S. Patent No. 6,269,810 (hereinafter referred to as "Brooker").

2. I graduated from Ohio State University in 1984 with a Bachelor of Science in Mechanical Engineering.

3. I am an inventor on multiple patents and patent applications in the area of pulmonary drug delivery, including U.S. Patent Nos. 6,269,810, 6,397,838, 6,796,303, and 6,805,118 and U.S. Patent Publication No. 2005/0236501.

4. Between 1984 and 1997, I held various positions at Chrysler Corporation, Cambridge Automation, Stratagene Cloning Systems, AMS Plastics, Inc. and Medex, Inc.

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5. In 1997, I co-founded Battelle Pulmonary Therapeutics, Inc. (now Ventaira, Inc.), where I was Vice President responsible for research and development as well as manufacturing of electromechanical aerosol delivery devices.

6. I am currently employed at Activaero America, Inc., where I became CEO at its inception in February 2007.

THE APPLICATION

7. I have read and understood the above referenced patent application, including the specification, claims and the relevant prior art.

8. The standard I used for anticipation is whether every element of a claim is disclosed in a single prior art reference.

9. The standard I used for obviousness is whether the claims would have been obvious to an ordinary person skilled in the art in light of the references cited.

10. Brooker discloses a device developed to deliver chemotherapy to patients in a hospital setting. Brooker discusses a pulsed nebulizer. The nebulizer was pulsed to avoid extraneous and potentially dangerous aerosolized chemotherapy agents from escaping from the device and exposing the patient and the caregiver.

11. An air pulse time in seconds is set manually before the start of treatment. Then the patient takes a pre-set number of inhalations to receive the total drug treatment. The air pulse is not varied from patient to patient.

12. Brooker does not teach or suggest a variable inhalation volume or variable flow rate. The aerosol quantity (concentration) is set by the pulse time but the volume is fixed as the aerosol is flowed into a fixed plenum. The flow rate through the device is fixed also and Brooker does not disclose a variable flow rate.

13. Brooker does not adjust respiratory flow rate.

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14. Instead, the only way to adjust breathing parameters at the time of Brooker was to try to teach patients to breathe correctly. For example, a respiratory therapist would always have his hand on the patient's back, to coach the patient to breathe correctly.

15. The concepts of controlling respiratory flow rate and tidal volume were not known at the time of Brooker. In addition, no one skilled in the art was aware of the concept of using controlled breathing via an external air source for a pulsed nebulizer system.

16. At the time, those skilled in the art were concerned with how much medicament was being delivered into the mouth, not where it went within the respiratory tract system. It was only possible to estimate total lung deposition with a very expensive scintigraphy procedure. In this procedure, the drug is radiolabelled, and then a gamma camera is used to estimate total lung deposition.

17. Therefore, Brooker does not disclose individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, adjusting flow rate or tidal volume based on inhalation parameters, or controlling an air flow through an inhalation device using the inhalation device during the controlled inhalation.

18. Even well trained pulmonologists typically are not familiar with the scientific background of aerosol particle deposition within the lungs.

19. In addition, even after extensive breathing training, patients typically revert to a respiratory flow rate and tidal volume that are comfortable to them. In clinical trials with conventional inhalation devices, it was shown that the incorrect breathing pattern is one of the most important errors that is made during inhalation treatment. (Giraud et al. 2002, 19:246-251, European Respiratory Journal, copy attached).

20. The Giraud reference specifically states that misuse of pressurized metered-dose inhalers is mainly due to poor coordination (see Abstract).

21. Controlled aerosol delivery to the lungs can only be guaranteed when inhalation parameters are inputted into the inhalation device, as claimed in claims 25, 43 and 44.

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CONCLUSION

Based on the above analysis, I conclude that the claims in the present patent application are not anticipated by or obvious over Brooker.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: August 1, 2008 By: William C. Zimlich, Jr.